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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/622,868	07/17/2003	Patrick F. Kelly	009.0049	2912

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EXAMINER

BERTRAM, ERIC D

ART UNIT	PAPER NUMBER
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3766

DATE MAILED: 06/20/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/622,868	Applicant(s) KELLY ET AL.	
	Examiner Eric D. Bertram	Art Unit 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 April 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-83 is/are pending in the application.
- 4a) Of the above claim(s) 9-16,26-34,43-71 and 74-83 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,17-25,35-42,72 and 73 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 17 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/17/03, 9/8/05</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Election/Restrictions

1. Applicant's election with traverse of Group I, claims 1-8, 17-25 and 35-42, in the reply filed on 4/21/2006 is acknowledged. The traversal is on the ground(s) that a search and examination of the entire application can be made without serious burden on the Examiner. This is not found persuasive because, regardless of the classification of the inventions, burden is established if a different field of search is necessary for the different inventions (see MPEP § 808.02). Specifically, the varying features of the inventions, including performing a physiological analysis, computing varying energy levels and utilizing multiple electrodes, would require divergent searches for the inventions in order to properly and completely examine the inventions, creating burden on the Examiner.

2. The applicant further argues that claims 58-60, 62, 63, 79, 81 and 83 do not include language that requires performance of a physiology analysis, and that independent claim 74 states that the shock "occurs without the external defibrillator conducting a physiology analysis of the patient." As stated in the Restriction requirement, Inventions V and VI are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed **can** be used to practice another and materially different process. (MPEP § 806.05(e)). While claims 58-60, 62, 63, 79, 81 and 83 may not require performance of a physiology analysis, the invention is still fully capable of performing

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one. Furthermore, while claim 74 may state that a physiology analysis is not conducted, this is viewed as functional language of the apparatus claims, and the invention is still fully capable of performing a physiology analysis.

3. The applicant further argues that the claims of group I do not include language directed to the energy level from which the shock takes place. While this may be true, Group II states that there must be a discharge to a second energy level prior to delivery of the defibrillation shock, while group I only recites charging the defibrillator and then applying the defibrillation shock, with no preliminary discharge prior to the shock. Therefore, the shock of Group I is inherently delivered from a first level, whatever that level may be, while the shock of group II is delivered from a second level after a preliminary discharge, as stated in the claims.

4. In the last paragraph of page 3 in the response, the arguments presented by the applicant in regard to groups I and IV have been found persuasive. As a result, group IV has been rejoined with elected group I. Groups II and III have not been rejoined with the elected invention due to the reasons presented in paragraphs 4 and 5 of the restriction requirement and the response to arguments presented above in paragraph 3.

The requirement is still deemed proper and is therefore made FINAL.

5. Claims 9-16, 26-34, 43-71, and 74-83 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

6. Claims 1-8, 17-25, 35-42, 72 and 73 are drawn to the elected invention and will be examined in this detailed action.

Information Disclosure Statement

7. The information disclosure statements (IDS) submitted on 7/17/2003 and 9/8/2005 were filed in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statements are being considered by the examiner.

Claim Rejections - 35 USC § 112

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 2, 3, 22, 36, 37, and 40-42 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In claim 1, it is stated that the charging began prior to initiating a physiology analysis. However, claim 2, which depends on claim 1, contains the limitation of "determining a rate to charging an energy storage device based at least in part upon said physiology analysis; and charging said energy storage rate at said rate." This is indefinite because claim 2 implies that the charging is dependent on the physiology analysis, while claim 1 states that the charging begins prior to the physiology analysis.

10. Claim 3 depends from claim 2, and as a result is indefinite by its association.

11. Regarding claims 22 and 40, the term "greater than" found throughout the claims is indefinite. It is unclear whether "greater than" means that a specific time instant is longer in length than another time instant, or if it means that a specific time instant occurs after another time instant. For examination purposes, the Examiner assumes that a time instant is "greater" if it occurs after another time instant.

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12. Regarding claims 36, 37 and 40-42, claim 36 recites the limitation "a first time instant", but is then followed by the symbol " (t_2) ", which implies a second time instant. This unclear wording and symbology renders the claim indefinite. For examination purposes, the Examiner assumes the applicant's meant to recite --a second time instant--.

13. Claims 37 and 40-42 depend from claim 36, and is rendered indefinite by its association.

Claim Rejections - 35 USC § 102

14. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

15. Claims 1-8 and 72 are rejected under 35 U.S.C. 102(b) as being anticipated by Cameron et al. (US 5,803,927, hereinafter Cameron). Cameron discloses a method of operating an external defibrillator such that an energy storage device begins to charge soon after the defibrillator is activated and prior to initiating a physiology analysis is initiated to detect a ventricular fibrillation (Col. 10, lines 14-19). After beginning to charge the energy storage device, a physiology analysis is initiated, and a defibrillation shock can then be automatically applied without human intervention. Alternatively, a defibrillation shock can be delivered in response to receiving a firing input from a human operator without a physiology analysis occurring (Col. 6, lines 39-42).

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16. Regarding claims 2-5, Cameron further discloses that once the precharge reaches a level of 1100 volts, it will remain at that level until a ventricular fibrillation is detected by the physiology analysis. Upon detection, the device will update the charging rate from zero and begin to charge the device to a level of 1650 volts at a predetermined rate (Col. 10, lines 14-24).

17. Regarding claim 6, Cameron further discloses that the defibrillator also determines the impedance of the patient (Col. 5, lines 42-54).

18. Regarding claim 7, Cameron discloses that the defibrillator utilizes an ECG system as part of its physiology analysis (Col. 6, lines 42-50).

Claim Rejections - 35 USC § 103

19. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

20. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

21. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of

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the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

22. Claims 17-25, 35-42 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cameron. Cameron discloses the applicant's basic inventive method, including initially activating the external defibrillator. Following activation, the defibrillator determines if ventricular fibrillation is present and determines to charge the capacitor to 1650 volts. The charge rate is automatically determined and the charge is initiated. A physiology analysis to determine the impedance of the patient begins as well. Finally the shock is delivered. Cameron does not disclose, however, exactly when the physiology analysis is completed in relation to completion of a rate determination. However, it would have been an obvious matter of design choice to determine a rate for charging an energy storage device in order to substantially achieve the charge after about a fifth time instant and before about a seventh time instant, since the method of Cameron discloses the same steps as the applicant, and produces the same results.

23. Regarding claims 20 and 38, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to modify the charge level of a defibrillation shock based on the transthoracic impedance of the patient because, based on Ohm's law, where $V=IR$, the voltage level V is can be proportionally changed with

respect to the impedance R of the system in order to result in an equivalent current delivery I .

24. Regarding claims 21 and 39, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to include a physiology analysis comprising an ECG analysis in order to determine how serious the fibrillation is, and thus modify the rate of charging based on this determination.

25. Regarding claim 73, Cameron does not specifically disclose that the firing input is disabled while the energy storage device is charging. However, it would have been obvious to one of ordinary skill in the art at the time of the applicant's invention to disable firing until the system is fully charged in order to deliver a fully charged, and thus most beneficial, defibrillation shock to the patient.

Conclusion


Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric D. Bertram whose telephone number is 571-272-3446. The examiner can normally be reached on Monday-Thursday and every other Friday from 9-6:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on 571-272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Eric D. Bertram
Examiner
Art Unit 3766



Robert E. Pezzuto
Supervisory Patent Examiner
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EDB